Food Safety
AUTHORITY OF IRELAND

Checklist for Food Supplement Establishment Inspections

This document should be read in conjunction with Guidance Note No 21 Revision 1 Food Supplements Regulations and Notifications and the Food Supplement Establishment Aide Memoire

October 2012

Food Supplement Establishment Inspection Checklist

Notes

1. This document should be used in conjunction with EHS 852 Visit Record, Food Supplements Aide Memoire, Guidance Note 21 Revision 1 Food Supplements Regulations and Notifications, Food Safety Authority of Ireland (FSAI) Training Booklet – Information on Nutrition and Health Claims and Food Supplements and other relevant legislation and guidance.
2. Further guidance on checks to be conducted is provided in the Food Supplement Aide Memoire. Section numbers and titles are the same as this checklist.
3. If any section is not applicable to the food business operator, record **N/A** in the scope column. If an applicable section was not inspected during this visit, record **N/S** in the scope column.
4. Cross references to Inspection Record 852 section number are indicated in brackets in the section title bars.

Types of Activities (tick all that apply)

Import ☐ Manufacture ☐ Sub-contract Manufacture ☐ Labelling ☐ Packing ☐ Distribution ☐ Export ☐ Retail ☐

Product Form: Tablet ☐ Liquid ☐ Capsule ☐ Powder ☐ Other _____

In-house Testing ☐ Sub-contract Testing ☐

Other product categories handled at the facility, e.g. food, pharmaceutical _____

Target population of food supplements _____

Comments_____

1	Product Range, Permitted Ingredients and Notifications	Scope	Status/Findings/Comments/Satisfactory?
1.1	Product Range		
1.2	Permitted Ingredients		
1.3	Food Supplement Notifications		
2	**Quality Management**	**Scope**	**Status/Findings/Comments/Satisfactory?**
2.1-2.4	Overview of QMS (GPP,QA & QC)		

3	Premises & Equipment (852 Visit Record A 1-6,B1, D2, 6 &7)	Scope	Status/Findings/Comments/Satisfactory?
3.1	Premises and Equipment		
3.2	Utilities/Services		
3.3	Equipment (including qualification of design & operation)		

4	Personnel and Training (852 Visit Record B2, B10 and D1, D8)	Scope	Status/Findings/Comments/Satisfactory?
4.1 & 4.2	General (personnel) and Training (training documents)		
4.3	Training of Food Supplement Handlers		
4.4	Personal Hygiene		

5	HACCP (852 Visit Record C 1-8)		Scope	Status/Findings/Comments/Satisfactory?
	Does the HACCP plan adequately address hazards and CCPs associated with food supplements as described in 5.1 - 5.9 of aide memoire?			

6	Product and Process Development	Scope	Status/Findings/Comments/Satisfactory?
6.1	General (change control and risk assessment)		
6.2	Legality and Safety of Ingredients		
6.3	Stability of Formula		
6.4	Labelling Compliance		
6.5	Claims Compliance		
6.6	Packaging Compliance		
6.7	Check it can be made Safely and Consistently (validation)		

7	Manufacture (852 B1,9,11-13,15, D4)	Scope	Status/Findings/Comments/Satisfactory?
7.1	General (including Deviations System)		
7.2	Suitability for Production		
7.3	Documentation		
7.4	Raw Materials and Ingredients		
7.5	Packaging Materials		
7.6	Processing and Packaging		
7.7	Intermediate Products		
7.8	Finished Products		
7.9	Disposal of Waste and Effluent		

8	Recovery and Reworking of Materials	Scope	Status/ Findings/Comments/Satisfactory?
8.1	Recovered, Reworked and Reprocessed Materials		
8.2	Returns		

9	Warehousing	Scope	Status/Findings/Comments/Satisfactory?
9.1	Storage Conditions		

10	Transport and Distribution (852 B 14)	Scope	Status/Findings/Comments/Satisfactory?
10.1	Transport Conditions		

11	Documentation	Scope	Status/Findings/Comments/Satisfactory?
11.1	General – Good Documentation Practices		
11.2	Types of Documents – Categories expected		
11.3	Retention		
11.4	Classes of Documents –List of expected Documents		

12	Complaints, Recall and Emergency Procedures (852 D 5)	Scope	Status/Findings/Comments/Satisfactory?
12.1	Complaints and Recalls		

13	Self Inspection	Scope	Status/Findings/Comments/Satisfactory?
13.1	Internal Audits		

14	Own Brand and Sub-contracting	Scope	Status/Findings/Comments/Satisfactory?
14.1	Contracted Activities		
14.2	Technical Agreements		

15	Laboratory Testing and Product Release	Scope	Status/Findings/Comments/Satisfactory?
15.1	Sub Contract Testing		
15.2	Accreditation		
15.3	Specifications		
15.4	Good Laboratory Practices		
15.5	Sampling		
15.6	Test Method Validation		
15.7	Inspection and Testing (record any samples taken)		
15.8	Stability and Shelf-life (record any samples taken)		
15.9	Handling Out of Specification (OOS) Results		
15.10	Product Approval and Release		

Signed: _____ Date: _____